

Listing of Claims:

Claims 1-47 (canceled).

48. (Currently amended) A process for preparing crystallized mirtazapine comprising the steps of:

- i) dissolving mirtazapine in an organic solvent, thereby forming a solution;
- ii) adding water to the solution; and
- iii) precipitating mirtazapine;

wherein the organic solvent is ethanol; and

wherein the yield of crystallized mirtazapine is about 90% or greater than 90%.

49. (Previously presented) The process of claim 48, wherein the yield is greater than 90%.

50. (Currently amended) The process of claim 48, wherein the yield is about 95% or greater than 95%.

51. (Previously presented) The process of claim 48, wherein the yield is greater than 95%.

52. (Previously presented) The process of claim 48, wherein the drying conditions comprise elevated temperature and reduced pressure.

53. (Previously presented) The process of claim 52, wherein the elevated temperature is about the reflux temperature of the organic solvent.

54. (Previously presented) The process of claim 48, wherein the dissolving step comprises refluxing the organic solvent.

55. (Previously presented) The process of claim 48, wherein the adding step comprises adding water dropwise to the solution.

56. (Previously presented) The process of claim 48, wherein the precipitating step comprises cooling the solution to about 10 °C.

57. (Previously presented) The process of claim 48,
wherein the dissolving step comprises refluxing the organic solvent;
wherein the adding step comprises adding water dropwise to the solution;
wherein the precipitating step comprises cooling the solution to about 10 °C; and
wherein the drying conditions comprise heating the precipitated mirtazapine to the reflux temperature of the organic solvent under reduced pressure.

58. (Previously presented) The process of claim 57, wherein the yield is greater than 95%.
59. (Currently amended) The process of claim 57, wherein the yield is about 95%, or greater than 95%.
60. (Currently amended) A process for preparing crystallized mirtazapine comprising the steps of:
- i) dissolving mirtazapine in an organic solvent, thereby forming a solution;
 - ii) adding water to the solution;
 - iii) precipitating mirtazapine; and
 - iv) drying the precipitated mirtazapine under conditions sufficient to produce crystallized mirtazapine having up to about 3% by weight water,
- wherein the yield of crystallized mirtazapine is about 90%, or greater than 90%.
61. (Previously presented) The process of claim 60, wherein the organic solvent is selected from the group consisting of methanol, ethanol, and isopropyl alcohol.
62. (Previously presented) The process of claim 61, wherein the organic solvent is ethanol.
63. (Previously presented) The process of claim 60, wherein the yield is greater than 90%.
64. (Currently amended) The process of claim 60, wherein the yield is about 95%, or greater than 95%.
65. (Previously presented) The process of claim 60, wherein the yield is greater than 95%.
66. (Previously presented) The process of claim 60, wherein the drying conditions comprise elevated temperature and reduced pressure.
67. (Previously presented) The process of claim 66, wherein the elevated temperature is about the reflux temperature of the organic solvent.
68. (Previously presented) The process of claim 60, wherein the dissolving step comprises refluxing the organic solvent.
69. (Previously presented) The process of claim 60, wherein the adding step comprises adding water dropwise to the solution.
70. (Previously presented) The process of claim 60, wherein the precipitating step comprises cooling the solution to about 10 °C.
71. (Previously presented) The process of claim 62,
- wherein the dissolving step comprises refluxing the organic solvent;
 - wherein the adding step comprises adding water dropwise to the solution;
 - wherein the precipitating step comprises cooling the solution to about 10 °C; and

wherein the drying conditions comprise heating the precipitated mirtazapine to the reflux temperature of the organic solvent under reduced pressure.

72. (Previously presented) The process of claim 71, wherein the yield is greater than 95%.

73. (Currently amended) The process of claim 71, wherein the yield is about 95%, or greater than 95%.

Remarks

Claims 48-73 are pending in the application. Applicants would like to thank the examiner for the courtesy of conducting an interview with Applicants' representative on July 12, 2005. During the interview an agreement was reached that if the rejected claims were amended as suggested by the examiner, then all of the pending claims would be allowable.

Rejections Under 35 USC § 112, Second Paragraph

Claims 48, 50, 59, 60, 64 and 73 have been rejected as indefinite in view of the phrase "about 90% or greater." Applicants respectfully disagree. However, to expedite prosecution, Applicants have made the non-narrowing amendment suggested by the examiner. Applicants therefore respectfully request the withdrawal of the foregoing rejection of claims 48, 50, 59, 60, 64 and 73.

Conclusion

In view of the foregoing remarks, Applicants respectfully request allowance of the pending claims. The Examiner is invited to contact the undersigned attorney to discuss any matter concerning this application. The Commissioner is hereby authorized to charge any fees which may be necessary for consideration of this paper to Kenyon & Kenyon Deposit Account No. 11-0600.

Respectfully submitted,

8/23/05
Date

O. Wallace
W. David Wallace
Reg. No. 42,210

KENYON & KENYON
1500 K Street, N.W., Suite 700
Washington, D.C. 20005
Telephone: 202-220-4200
Facsimile: 202-220-4201